[FPH Regional Office details]

[Date]

Chief Executive Officer
[Facility Address]

Attention: All users and operators of MR290 Autofeed Humidification Chambers

MR290 Urgent Field Safety Notice

Fisher & Paykel Healthcare MR290 Autofeed Humidification Chamber (all batch/lot numbers)

FPH Urgent Field Safety Notice: FA-2012-001

DEPTH OF FIELD SAFETY NOTICE:

- Consumer level

REASON FOR FIELD SAFETY NOTICE:

Fisher & Paykel Healthcare (FPH) has become aware that there is a possibility that the MR290 Autofeed Humidification Chambers may be susceptible to cracking when they come into direct contact with cleaning agents which contain solvents.

FPH would like to remind customers that the MR290 is a single use device. All personnel responsible for use and set up of the FPH MR290 chamber should refrain from cleaning the chambers and should also not handle chambers while their hands are wet after using cleaning agents, including hand sanitisers.

AFFECTED PRODUCT DETAILS

The MR290 Autofeed Humidification Chamber is a component of the Fisher & Paykel Healthcare MR850 Humidification System and is also used with the AIRVO series. The MR290 chamber provides optimal humidified gases to patients, maintaining secretion quality, promoting gas exchange and decreasing the risk of infection.

The chambers are sold individually (in a box of 10 or 40) or as part of kit (see below 'Part Numbers/Model').

Figure 1: MR290 Autofeed Humidification Chamber

NAME OF PRODUCT:

- Fisher & Paykel Healthcare MR290 Autofeed Humidification Chambers:
    - Vented Autofeed Humidification Chamber/Infant Humidification Chamber
    - High Frequency Vented Autofeed Adult/Infant Humidification Chamber

PART NUMBERS / MODEL:

- MR290V, MR290VX and MR290HFV
- The following products contain an MR290 chamber as part of a kit:
  900PT501, BC151-10, BC161-10, BC171-10, BC461-SK, BC471-SK, BC469-VZ, RT200, RT201, RT202, RT203, RT204, RT205, RT206, RT210, RT211, RT212, RT215, RT219, RT224, RT225, RT226, RT228, RT235, RT236, RT240, RT241, RT265, RT266, RT267, RT268, RT307, RT308, RT319, RT324, RT329, RT340, RT345, RT350, RT380, RT385, RT401, RT408, RT411, RT443.

LOT NUMBER / SERIAL NUMBER:

- All LOT number and batches.

ACTIONS REQUIRED FROM YOU:

Transmission of this Field Safety Notice

Please transfer this notice to all those who need to be aware within your organization. If affected product has been distributed to any other organization or patients/users, please notify them with a copy of this letter regarding this Field Safety Notice **within 15 working days** upon receipt of this notice.

Please be advised that Fisher & Paykel Healthcare has notified all appropriate Regulatory Agencies of this Field Safety Notice as required, including [insert Regulatory Agencies]. If you have any questions relating to the above actions do not hesitate to contact your Fisher & Paykel Healthcare Representative [insert name] or myself.

Yours Sincerely,
[Signature]
[Insert EU sponsor name, position details, email]